Co-Site Visit Report

Run by :

Audit Date :
Group :
Audit Category :
Audit Type :
Institution Code :
Name :
Member Study type:
Main Member / CCOP Code :
Name :
Audit Location :
Revision Number:
Revision Date:

Number of Cases Audited :
Principal Investigator :
Number of Protocols Reviewed :

Co-Site Auditor Information

Name	Title	Affiliation

Audit Outcome Summary

Component	Assessment
IRB and Informed Consent Content Assessment	
Accountability of Investigational Agents and Pharmacy Operations Assessment	
Review of Patient Case Records Assessment	

Audit Date : Group : Audit Category : Audit Type :
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Audit Location :
Revision Number: Revision Date:

I. IRB and Informed Consent Content Review:

A. IRB Review	Finding	Comments
1. Were each of the selected protocols and informed consents available at the site?		
2. Was the most up-to-date version of the protocol and informed consent available?		
3. Did the auditors review IRB documentation at the site or off-site?		
4. Were the protocols reviewed for initial IRB approval?		
5. Were all annual re-approvals reviewed by the IRB in a timely manner?		
6. Were all amendments reviewed and approved by the IRB?		
7. Did the auditors follow CTMB guidelines?		
8. Did the auditors conduct an adequate IRB review?		

B. Informed Consent Content (ICC) Review:

1. Were locally used informed consents reviewed?

2. Were local informed consent documents reviewed onsite or offsite?

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3. Did the auditors conduct an adequate informed consent content review?

C. IRB and Informed Consent Content Assessment :

II. Accountability of Investigational Agents and Pharmacy Operations Review:

	Finding	Comments
1. Were INDs and /or NCI supplied agents used at this site during the time period covered by this audit?		
2. Was the pharmacy visited?		
3. Are NCI DARFs in routine use?		
4. Were NCI DARFs reviewed on-site or off-site?		
5. Was the pharmacy inspected according to CTMB guidelines?		
6. Was there adequate security?		
7. Were satellite NCI DARFs reviewed?		
8. Did the auditors conduct an adequate Pharmacy/DARF review?		

Accountability of Investigational Agents and Pharmacy Operations Assessment :

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III. Patient Case Review:

	Finding	Comments
1. Were patient informed consent documents reviewed?		
2. Were any major informed consent deficiencies noted?		
3. Was each audited case reviewed for eligibility?		
4. Were any major eligibility deficiencies noted?		
5. Were any major treatment deviations noted?		
6. Were any major response/disease outcome discrepancies noted?		
7. Were any major toxicity deficiencies noted?		
8. Were any major data quality deficiencies identified?		
9. Were the materials available for the audit adequate?		

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10. Did the auditors conduct an adequate review in accordance with CTMB guidelines?

Review of Patient Case Records Assessment :

Exit Interview

1. Was the exit interview attended by the PI? :

2. Were the preliminary audit findings stated and discussed? :

3. Were Group recommendations made? If "Yes", explain below. :

4. Did the auditors conduct an adequate exit interview? :

Exit Interview Comments :

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General Comments:

1. Was the audit conducted according to CTMB Guidelines? :

Overall Comments and Recommendations :

Prepared By Date

Approved By Date